

PATENT APPLICATI

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Attorney Docket No.: 3364.25US01

Hinz

Confirmation No.: 8497

Application No.:

10/785,158

Examiner: Unknown

Filed:

February 23, 2004

Group Art Unit: 1614

For:

SEROTONIN AND CATECHOLAMINE SYSTEM SEGMENT OPTIMIZATION

**TECHNOLOGY** 

# SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. § 1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached Form PTO-1449. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The listing of a reference herein is not an admission that the reference is prior art or that the reference is material to patentability.

This information is being filed before the mailing date of a first Office Action on the merits. No certification or fee is required. This application was filed after June 30, 2003; therefore, copies of cited U.S. patents and U.S. published applications are not included.

Respectfully submitted,

Brian L. Stender

Registration No. 56,836



Application No. 10/785,158

Customer No. 24113
Patterson, Thuente, Skaar & Christensen, P.A. 4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100

Telephone: (612) 252-1548

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 16-0631.

### CERTIFICATE OF MAILING

I hereby certify that this document is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

April 7, 2006

Date of Deposit

Brian L. Stender

2

- 100											
Substitute for form 1449/PTO SUPPLEMENTAL INFORMATION					L			olete if Known			
					Application Number 10			10/785,158			
SUP EMENTAL INFORMATION						ling Date	Feb	February 23, 2004			
RA S	DISCLOSURE ATEMENT BY APPLICANT					rst Named Inventor	Martin C. Hinz				
ATENT & TRA						t Unit	1614	1614			
(Use as many sheets as necessary)					Examiner Name		Unk	Unknown			
Sheet	T 1	1 of 5						364.25US01			
Sheet						TENT DOCUMENTS					
CVANADIED	Cita	· · · · ·		U.S. PATER	11	Publication Date		Name of Detentes on Applica			
EXAMINER INITIAL	Cite No. <sup>1</sup>	Document Number  Number-Kind Code <sup>2 (if known)</sup>				MM-DD-YYYY		Name of Patentee or Applicant of Cited Document			
			001/0002269			05-31-2001		Zhao			
		US-2001/0008641 US-2001/0008884 US-2001/0020007 US-2002/0147206				07-19-2001 07-19-2001 09-06-2001		Krotzer			
								Worsley			
								Wiss			
						10-10-2002		Howard, Jr.			
		US-2002/0187958 US-2004/0071681				12-12-2002		Horrobin et al.			
						04-15-2004		Muller			
		US-2	004/0077556	5		04-22-2004 Chinery		Chinery			
		US-2	004/0081678	3		04-29-2004		Cincotta			
	,	US-2	004/0116351			06-17-2004		Halevie-Goldman			
		US-2	004/0151771			08-05-2004		Gin et al.			
		US-2	004/0247669	)		12-09-2004		Gin et al.			
*		US-2005/0233014				10-20-2005		Lee et al.			
D		US-2005/0287226 US-3,097,947 US-4,237,118				12-29-2005		Sisco et al. Kemmerer			
						07-16-1963					
						12-02-1980		Howard			
		US-4,397,866				08-09-1983		Wurtman			
		US-5,019,594 US-5,480,657				05-28-1991	Wurtman et al.				
						01-02-1996		Allen			
			,795,895			08-18-1998	Anchors				
			,977,099			1-02-1999 Nickolson		Nickolson			
		<del></del>	,207,699			03-27-2001		Rothman	-		
		<del></del>	,660,777	· · · · · · · · · · · · · · · · · · ·		12-09-2003		Hinz			
	<u> </u>	<del></del>	<del></del>	OREIGN PAT	ΓEN	IT DOCUMENTS					
EXAMINER INITIAL*	Cite No. <sup>1</sup>	Foreign Patent Documen				Publication Date MM-DD-YYYY		Name of Patentee or Applicant			
		Со	untry Code <sup>3</sup> Nun (if kno	nber <sup>4</sup> Kind Code <sup>5</sup> wn)				of Cited Document			
		JP100	067663A2			03-10-1998		Nickolson			
EXAMINER						DATE	1				

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include

**SIGNATURE** 

**CONSIDERED** 

copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.

#### Complete if Known Substitute for form 1449/PTO 10/785,158 Application Number February 23, 2004 SUPPLEMENTAL INFORMATION Filing Date DISCLOSURE First Named Inventor Martin C. Hinz STATEMENT BY APPLICANT Art Unit 1614 (Use as many sheets as necessary) **Examiner Name** Unknown 3364.25US01 2 5 Attorney Docket Number of Sheet NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item **EXAMINER** Cite INITIAL\* No.1 (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published ABELL ET AL., "Placebo Controlled Double-Blind Trial of Fluvoxamine Maleate in the Obese" Journal of Psychosomatic Research, 30(2): 143-146 ACN Annual Meeting, San Juan, Puerto Rico, Dec. 15, 2000, PRNewswire (Abstract). AGUNDEZ ET AL., "Modulation of CyPIA2 enzyme activity by indoleamines: inhibition by serotonin and tryptamine", Pharmacogentics, 8:251-258 (1998). Anchors Book, "Safer Than Phen-Fen" Anchors (Ed.), page 82. ANDREWS ET AL., "The Effects of 5-hydraoxytryptophan and 5hydroxytryptamine on Dopamine Synthesis and Release in Rat Brain Striatal Synaptosomes", Journal of Neurochemistry, 30:465-470 (1978). AVARELLO, "Serotonin Syndrome: a reported case", Neuro Sci. 23:S55-S56 (2002).BARTHOLOME ET AL., "L-dopa and 5-hydroxytryptophan Therapy in Phenlalanine-Hydroxylase Activity", The Lancet 2 (Nov. 22): 1042-1043 (1975). BAUMANN ET AL., "Transport Mechanisms for the Antidepressant Citalopram in Brain Microvessel Endothelium", Brain Res. 831(1-2); 229-36 (1999) (Abstract). BOUCHARD ET AL., "Citalogram and Viloxazine in the treatment of depression by means of slow drop infusion A double-linked Comparative Trial", Journal of Affective Disorders 46:51-58 (1997). COPPEN ET AL. "Levodopa and L-tryptophan Therapy in Parkinsonism", The Lancet, March 25, 1972. Drug Facts and Comparison 1999 Edition, Riley (ed). DUNNER ET AL., "Affective Disorder: Studeis with Amine Precursors", Am J. Psychiatry 132(2): 180-183 (1975). FAVA, "Weight Gain and Antidepressants", J. Clin Psychiatry, 61 (Suppl 11 (1-2):37-41 (2000)(Abstract). **EXAMINER** DATE

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

CONSIDERED

**SIGNATURE** 

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

								_			
Substitute for form 1449/PTO					Complete if Known						
					Applicat	ion Number	10/785,158				
SUPPLEMENTAL INFORMATION DISCLOSURE						ate	February 23, 2004				
						ned Inventor	Martin C. Hinz				
STATEMENT BY APPLICANT (Use as many sheets as necessary)					Art Unit		1614				
					Examine	r Name	Unknown				
Sheet	3		of	5	Attorney	Docket Number	3364.25US01				
			NON P.	ATENT LITE	ERATU	RE DOCUME	NTS				
EXAMINER INITIAL*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item									
		disor	FAVA ET AL., "Fluoxetine versus sertraline and paroxetine in major depressive disorder: changes in weight with long-term treatment", <u>J. Clin. Psychiatry</u> , 61(11): 863-7 (2000) (Abstract).								
		1	FOGLIA ET AL., "Plasma levels of citalopram enantiomers and metabolites in ederly patients", Psychopharmacol Bull, 33(1):109-12 (1997) (Abstract).								
***		GELENBERG ET AL., "Tyrosine for the treatment of depression", Nutr. Health, 3(3):163-73 (1984).									
		HARVEY ET AL., "Neuropharmacology of paradoxic weight gain with selective serontonin reuptake inhibitors", <u>Clin Neuropharmacol</u> , 23(2):90-7 (Mar-Apr 2000) Abstract.									
-		HURLEY ET AL., "Pyrrolo [1,4] benzodiazepine Antibiotics. Biosynthesis of the Antitumr Antibiotic 11-DemethyItmaymycin and its Biologically Inactive metabolity Oxotomaymycin to Streptomyces achromogene, Biochemistry, 15(17):3760-3769 (1976).  KRAMARCY ET AL., "Effects of Drug-Inducted Changes in Brain Monoamines on Aggression and Motor Behavior in Mice", European Journal of Pharmacology, 99:141-151 (1984).									
٥											
		LEINONEN ET AL., "Efficacy and tolerability of mirtazapine versus citalopram: a double-blind randomized study in patients with major depressive disorder. Nordic Antidepressant Study Group", Int. Clin Psyopharmacol., 14(6):329-37 (1999) (Abstract).									
		LI KAM WA ET AL., "Renal metabolism and effects of the glutamyl derivates of L-dopa and 5-dydroxytryptophan in man", Clinical Science, 91:177-185 (1996).									
		Panci	LINDSTROM, "Aromatic-L-Amino-Acid Decarboxylase Activity in Mouse Pancreatic Islets", Biochimica et Biophysica Acta, 884:276-281 (1986).								
		LINDSTROM, ET AL., "Aromatic amino acids and pancreatic islet function: a comparison of L-tryptophan and L-5-hydroxytryptophan", Molecular and Cellular Endocrinology, 48:121-126 (1986).									
EXAMINER SIGNATURE				DATE CONSIDERED							

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.

S	ubstitut	te for form 1449/F	OTO	Complete if Known						
				Application Number	10/785,158					
SUP		ENTAL INFORM	ATION	Filing Date	February 23, 2004					
a m		DISCLOSURE	4.3.100	First Named Inventor	Martin C. Hinz 1614					
ST		ENT BY APPLIC  many sheets as necessary,		Art Unit						
	(	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		Examiner Name	Unknown					
Sheet	4	of	5	Attorney Docket Number	3364.25US01					
		NON	PATENT LITE	ERATURE DOCUME	ENTS					
EXAMINER INITIAL	le (when appropriate), title of the item s), volume-issue number(s), publisher, ed	T <sup>2</sup>								
		MALONE ET AL., "Treatment (Rx) of 76 Pateitns with Primary Fibromyalgia (1° FM) with Combined Dopaminergic and Serotonergic Drugs", Arthritis & Rhuematism, 39:S92 (1992) (Abstract).  MAREK ET AL., "A comparison of trazodone and fluoxetine: implications for a serotonergic mechanis of antidepressant action", Psychopharmacology 109:2-11								
		(1992).  MATHIAU ET AL, "Absence of Serotonergic Innervation from Raphe Nuclie in Rat Cerebral Blood Vessels – II. Lack of Trypthophan Hydroxylase Activity In Vitro" Neuroscience, 52(3): 657-665 (1993).								
		The Medical Letter, "Fluoxetine (prozac) and Other Drugs for Treatment of Obesity" Abranowics et al (Ed.)  The Merck Index, Budavari et al., (Ed.)								
		The Melek mae.	k, Budavaii et a	ai., (Eu.)						
À		MEYERS, "Use of Neurotransmitter Precursors for Treatment of Depression", Alternative Medicine Review, 5(1):64-71 (2000).								
			•		of Fluvoxamine Versus ", <u>BJCP</u> , 45(4): 259-262					
					cid decarboxylase from a gia, 91(4):61-26 (1999)					
				n Administration in Lonsonian Patients" Ger	-					
		SAWAKI ET AL., "Some correlations between Procaine-Induces Convulsions and Monamines in the Spinal Cord of Rats", <u>Japan</u> , J. <u>Pharmacol</u> , 51:369-376 (1989).								
EXAMINER				DATE						

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

**SIGNATURE** 

CONSIDERED

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.

#### Complete if Known Substitute for form 1449/PTO **Application Number** 10/785,158 Filing Date February 23, 2004 SUPPLEMENTAL INFORMATION DISCLOSURE First Named Inventor Martin C. Hinz STATEMENT BY APPLICANT Art Unit 1614 (Use as many sheets as necessary) **Examiner Name** Unknown Attorney Docket Number 3364.25US01 Sheet of NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item **EXAMINER** Cite INITIAL\* No.1 (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published SCHLOSBERG ET AL., "Effects of L-Dopa and L-5-Hydroxytryptophan on Locomotor Activity of the Rat after Selective or combined destruction of Central Catecholamine and Serotonin Neurons", The Journal of Pharmacology and Experimental Therapeutics, 211(2):296-304 (1979). SHINTAKU ET AL., "Diagnosis and treatment of 6-pyruvoyl-tetrahydropterin synthase deficience", Brain & Development, 22:S118-S121 (2000). STERNBERG ET AL, "Development of Scleroderma-like Illness during Therapy with L-5-hydroxytryptophan and Carbidopa", The New England Journal of Medicine, 303(14):782-787 (1980). TANAKA ET AL., "Hyperphenylalaninemia Due to Impared Dihydrobiopterin Biosynthesis", Eur. J. Pediatr, 136:275-280 (1981). THURMOND ET AL, "Effects of Dietary Tyronsine, Phenylamlanine, and Tryptophan on Aggression in Mice", Pharmacoogy Biochemistry & Behavior, 6:475-478 (1977). TRULSON ET AL., "Behavorial Effects of Serotonergic and Dopaminergic Drugs in Cats Following Chronic Amphetamine Administration", European Journal of Pharmacology, 99:313-324 (1984). WEITBRECHT ET AL., "Der Einfluss von l-Tryptophan auf die L-Dopa-Resportion", Dtsch Med Wochenschr, 101(1): 20-22 (1976). Neuroscience Litigation Pleadings Dave Peterson Affidavit (April 11, 2005) DATE **EXAMINER CONSIDERED SIGNATURE**

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.